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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,989	03/30/2006	Heinz Von Der Kammer	37998-237373	9161
26694	7590	10/03/2007		
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER HIRIYANNA, KELAGINAMANE T	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 10/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/573,989	Applicant(s) VON DER KAMMER ET AL.	
	Examiner Kelaginamane T. Hiriyanne	Art Unit 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-13, 16 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13, 16 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's response filed on 07/10/2007 in response to office action mailed on 04/10/2007 has been acknowledged.

Claims 11-13, 16 and 29 are amended.

Claims 25 and 26 are cancelled.

Claims 1-0, 14-15, 17-24, 27-28 and 30 are withdrawn.

*Claims 11-13, 16, and 29 are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

Claims 11-13, 16, and 29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reason of record as set forth in the previous office action mailed on 04/10/2007.

#### **Response to Arguments of 07/10/2007:**

Applicant amends claims and argues that as amended the instant claims should overcome the rejection.

The Applicants arguments are however found not persuasive because the scope of the invention as amended still encompasses any fragment or any variant of sulfotransferase family 4A member 1 gene, transcription product of said gene, or translation product of said transcripts. Further Said fragments as defined could be of any size, still further said variants as defined refers to any mutant gene, any splice variants, any mutant transcripts or edited transcripts and their translation products. The specification only describes the two splice variants of SULT4A1 gene transcripts (SEQ ID

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Nos: 1-2). The specification does not describe sufficient number of variants of SULT4A1 or said SULT4A1-substances. Since the specification fails to disclose other claimed variants and fragments of SULT4A1 gene and the gene products one of ordinary skill in the art would not recognize that the inventor was in possession of the invention as broadly claimed. Hence the rejection is maintained.

Claims 11-13, 16, 25-26 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for a modulator of SULT4A1 (SEQ ID Nos:1-2) activity in an isolated cell or using a SULT4A1 transgenic or SULT4A1 gene disrupted *Drosophila* or a mouse, does not enable a modulation of any neurodegenerative disease in any animal, does not enable modulation of any SULT4A1 variants by using any methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reason of record as set forth in the previous office action mailed on 04/10/2007.

**Response to Arguments of 07/10/2007:**

Applicant amends claims and argues that as amended the instant claims should overcome the rejection.

The Applicants arguments are however found not persuasive because the scope of the invention as amended still encompasses identifying any fragment or any variant of sulfotransferase family 4A member 1 gene, transcription product of said gene, or translation product of said transcripts that are modulated by a compound. Further Said fragments as defined could be of any size, still further said variants as defined refers to any mutant gene, any splice variants, any mutant transcripts or edited transcripts and their translation products. The specification only describes an analysis of differential expression of SULT4A1 gene that occurs naturally in brain tissues of diseased human Alzheimer's patients as indicated by the analysis of post-mortem brain tissues. The only modulation of SULT4A1 gene expression in a living animal described in the specification is by done by SULT4A1 transgene expression in a cell or in a transgenic mouse or *Drosophila* and by SULT4A1 gene targeted mouse and *Drosophila* and the only variants

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described are the two splice variants of SULT4A1 gene transcripts (SEQ ID Nos: 1-2). The specification does not describe the modulation of sufficient number of examples of variants and fragments of said SULT4A1-substances. Since the specification fails to disclose other claimed variants and fragments of SULT4A1 gene and the gene products and their modulation in any animal one of ordinary skill in the art would not recognize that the inventor was in possession of the invention as broadly claimed. Hence the rejection is maintained to the extent it encompasses variants and fragments.

### **Claim Rejections - 35 USC § 102**

Claims 11-12, 16, and 29 stand rejected under 35 USC 102 (b) as being anticipated by Farb et al., (WO 02/18541) for the reason of record as set forth in the previous office action mailed on 04/10/2007.

The above claims are directed to a method for screening for a modulator of Alzheimers associated with SULT4A1 gene, transcript, protein or derivatives and variants thereof by contacting a cell or animal with a test compound and measuring the alteration in the level of activity or said SULT4A1 or level of said SULT4A1 gene, transcript, protein or derivatives and variants thereof.

### **Response to Arguments of 07/10/2007:**

The Applicant amends claims and argues that as amended the instant claims should overcome the rejection. The Applicant further argues that the Farb reference does not teach method of screening for a modulator of Alzheimers disease.

The Applicants argument however found not persuasive because Farb clearly teaches method of treating (modulating) Alzheimers disease comprising administering SULT4A1 polypeptide (modulator). The said modulator increases the sulfotransferase activity when provided to a cell (p.41, paragraphs 2-3). Further Farb clearly teaches method of measuring SULT4A1 sulfotransferase enzyme and its expression by its ability to bind PAP-Agarose and by its activity to form sulfate groups on small neuro-chemicals (p.4, lines 1-27). The cited art thus anticipates the invention as claimed. Hence the rejection is maintained.

### **Conclusion:**

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No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Friday from 9 AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.



Kelaginamane T. Hiriyanna

Patent Examiner

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SUMESH KAUSHAL, PH.D.  
PRIMARY EXAMINER